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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	Group Art Unit:
Steven C. Quay	Examiner:
Appln. No. NEW	INFORMATION DISCLOSURE STATEMENT
Filed: HEREWITH	2001 Ferry Building San Francisco, CA 94111
For: METHOD OF ULTRASOUND IMAGING	

EXPRESS MAIL CERTIFICATE

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Service" Label No. EM393841454US, postage paid in an envelope, addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on July 16, 1997

Dated: 7-18-97 By: LIMBACH & LIMBACH, L.L.P. HOWARD WONG

Assistant Commissioner
for Patents
Washington, D.C. 20231

Sir:

Applicant submits herewith patents, publications or other information [attached hereto and listed on the attached Form PTO-1449 (modified)] of which he is aware, which he believes may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR § 1.56.

This Information Disclosure Statement:

(a) [X] accompanies the new patent application submitted herewith. 37 CFR § 1.97(a).

(b) [] is filed within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 CFR § 1.491.

(c) [] as far as is known to the undersigned, is filed before the mailing date of a first Office action on the merits.

(d) [] is filed after the first office action and more than three months after the application's filing date or PCT national stage date of entry filing but, as far as is known to the undersigned,

application's filing date or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever occurs first, and is accompanied by either the fee ($210) set forth in 37 CFR § 1.17(p) **or** a certification as specified in 37 CFR § 1.97(e), as checked below.

(e) [ ] Is filed after the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee ($130) set forth in 37 CFR § 1.17(i)(1) and a certification as specified in 37 CFR § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the Information Disclosure Statement.

[If either of boxes (d) or (e) are checked above, the following "certification" under 37 CFR § 1.97(e) may need to be completed.] The undersigned certifies that:

(f) [ ] Each item of information contained in the Information Disclosure Statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

(g) [ ] No item of information contained in this Information Disclosure Statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

A list of the patent(s) or publication(s) is set forth on the attached Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith:

(h) [ ] Each (i) [x] None (j) [ ] Only those listed below:

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO Form 1449 are not supplied because they were previously cited by or submitted to the Office in a prior application No. 08/770,522, filed December 20, 1996 which is a continuation application of application No. 08/649,910, filed May 16, 1996 which is a continuation application of 08/380,085 filed January 30, 1995, now U.S. Patent No. 5,558,854 which is a divisional application of 07/936,011 filed September 2, 1992 which is a continuation-in-part application of 07/893,657 filed June 5, 1992, now U.S. Patent No. 5,409,688 which is a continuation-in-part application of 07/761,311 filed September 17, 1991, and relied upon in this application for an earlier filing date under 35 U.S.C. 120.

A concise explanation of relevance of the items listed on PTO-1449 is:

(k) [ ] Not given

(l) [ ] Given for each listed item

(m) [x] Given for only non-English language listed item(s) [Required]

(n) [ ] Is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In "Ultrasound Contrast Media, Processes for Their Production and Their Use as Diagnostics and Therapeutics" (**EP 327490**) Stein, et al. disclose ultrasound contrast media consisting of micro particles which consist of amyloses or synthetic, biodegradable polymers and a gas and or a liquid with a boiling point below 60 degrees C, processes for

their production and use as diagnostics and therapeutics.

In "Ultrasound contrast agent, vaccine, diagnostic or therapeutic agent - comprising micro-particulate polyelectrolyte complex and at least one active agent," (**EP 454044**), Groner, Hoffmann, Krone, Magerstadt, Walch disclose a pharmaceutical composition containing a polyelectrolyte complex of a microparticulate form and at least one active agent. For ultrasound imaging, the active agent contains two components including a polymer and have an average size of up to five microns.

In "Echo contrast agent for ultrasound diagnosis of left ventricle - comprises aqueous preparation containing polyoxyethylene-polyoxypropylene polymers and negatively charged phospholipid(s) for uptake and stabilization of micro gas bubbles," (**DE 4100470**), Beller, Linder disclose an aqueous preparation for the stabilization of microbubbles of gas for use as an ultrasound contrast agent containing polyoxyethylene polyoxypropylene polymers and negatively charged phospholipids. The microbubbles are formed from air.

In "Ultrasonic Contrast Medium Comprising Gas Bubbles and Solid Lipophilic Surfactant-containing Microparticles and Use Thereof," (**DE 3834705**) Hillman, et al. disclose microparticles which are less than 12 microns in size which comprise a solid lipophilic group-containing compound having an HLB value less than about 20 for use in ultrasound contrast.

In "Contrast media for ultrasonic diagnosis - contains emulsion of fluorocarbon, emulsifying agent, e.g. phospholipid(s) and nonionic polymeric surfactant," (**JP 2196730**), Green Cross Corporation discloses an ultrasound contrast agent comprising an emulsion of a fluorocarbon having bromine substituted for one or two fluorine atoms, and an emulsifying

agent chosen from phospholipids and non-ionic polymeric surfactants. The particle size ranges from 0.05 to 0.4 microns. The fluorocarbons do not undergo a phase transition from a liquid to a gas below 37 degrees C.

In "Cardiological ultrasound diagnosis - involves intravenous injections of lipid emulsion of contrasting compound and physiological solution," (**SU 1641280**), Gelfgat, Rystamov disclose a method of imaging involving injecting a 20% lipidic soybean oil emulsion with a particle dispersed phase less than one micron. No English-language version of this complete document was readily available to applicant. An English-language abstract is submitted.

In "Enhancement of Hepatic tumor with helium gas microbubbles: A preliminary report." **(JPN J. Med. Ultrasonics 18:(5): 444-445 (1991)**, Nomura, et al. describe the use of helium microbubbles as an ultrasound contrast agent. An English language translation of this document is submitted.

The Examiner is reminded that a "concise explanation of the relevance" of the submitted items "may be nothing more than identification of the particular figure or paragraph of the patent or publication which has some relation to the claimed invention," MPEP § 609.

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR § 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR § 1.56(a) exists. It is submitted that the Information Disclosure Statement is in compliance

with 37 CFR § 1.98 and MPEP § 609 and the Examiner is respectfully requested to consider the listed references.

[x] The Commissioner is hereby authorized to charge our Deposit Account No. 12-1420 for any fees required in connection with the filing of this Information Disclosure Statement. **A duplicate copy of this Notice is enclosed for this purpose.** In particular, in the event that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is authorized to charge the above-named deposit account for any fees required pursuant to CFR §§ 1.17(p) or 1.17(i)(1).

Respectfully submitted,
LIMBACH & LIMBACH L.L.P.

By: _____
W. Patrick Bengtsson
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Our File: SNUS-125